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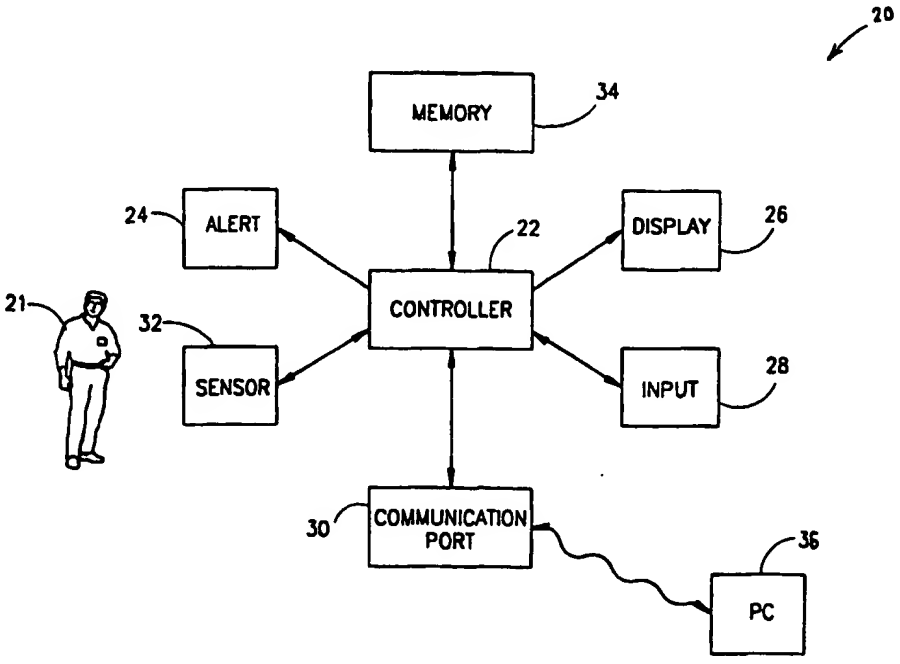

(57) Abstract

An ambulatory monitor (20) is used to increase patient compliancein medicine taking, reporting side effects, disease progress, symptoms, and/or the effect of treatment. The preferred embodiment includes the monitor (20), an alert generator (24), a controller (22), a display (26), a sensor/accelerometer (32), and a communication port (30) for the patient (21).

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AMBULATORY MONITOR

RELATED APPLICATIONS

This application claims the benefit under 119(e) of US provisional application 60/121,290, with like title and filed on February 22, 1999, the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ambulatory monitors, especially for tracking the progress of diseases and the effectiveness of medical treatments.

BACKGROUND OF THE INVENTION

Ambulatory patient monitors, also of types that automatically measure signals, are known. For example, one such device is described in U.S. Patent 4,354,375, the disclosure of which is incorporated herein by reference. U.S. Patent 5,293,879 and an article "Ambulatory Monitoring of Tremor and Other Movements Before and After Thalamotomy: A New Quantitative Technique", by EJW van Someren, WA van Gool, BFM Vonk, M Mirmiran, JD Speelman, DA Bosch and DF Swaab, in Journal of Neurological Sciences, 117 (1993) pp. 16-23, the disclosures of which are incorporated herein by reference, suggest using an ambulatory for monitoring Parkinson's disease. In the latter patent, it is suggested that the monitor automatically administer a pharmaceutical to a patient.

U.S. Patent 5,642,731, the disclosure of which is incorporated herein by reference, describes a portable device for reminding a patient to take medicine and for querying a patient (to some extent) regarding side effects. This patent describes a device that is large enough to hold one or more types of pills. A non-portable device for reminding a patient to take a blood test is described in U.S. Patent 5,442,728, the disclosure of which is incorporated herein by reference.

A disadvantage the pill-box device is that it must be carried around, as it is apparently too large to be worn. Consequently, patient compliance may be compromised, for example if the patient has no pockets in his apparel or if the patient is embarrassed or inconvenienced by carrying the pill-box around. If a patient does not carry the pill-box, he will not get any reminders, answer questions and/or otherwise be monitored.

SUMMARY OF THE INVENTION

An object of some preferred embodiments of the invention is to increase patient compliance in medicine taking and/or in reporting side effects, disease progress, symptoms and/or the effect of treatment. In a preferred embodiment of the invention, this increase in

compliance is achieved by providing the patient with a device that is worn, preferably a wristwatch-like device.

An object of some preferred embodiments of the invention is to increase a confidence level of a patient's subjective reports by providing objective data which can be compared with the subjective record of the patient.

An object of some preferred embodiments of the invention is to shorten pharmaceutical clinical trials and/or improve their credibility by enhancing the acquisition of patient data, especially with regard to side effects and treatment efficacy. In a preferred embodiment of the invention, data acquisition is enhanced by questioning the patient using focused queries. Preferably, the queries are structured and/or dependent on previous responses. Additionally or alternatively, the queries take into account data which is logged by an ambulatory monitor, either automatically or manually.

One aspect of some preferred embodiments of the invention relates to a patient querying device which is worn by the patient. In a preferred embodiment of the invention, the device is worn on a wrist, preferably having an exterior similar to a wrist-watch, possibly incorporating the functionality of a wristwatch. Alternatively, the device may be worn as a necklace and/or on a chain or cord around the neck. In a preferred embodiment of the invention, the device includes a display, which displays various information, including one or more of a query, a reminder, a time, processed and/or sensed data and/or an indication of a response by the patient. Alternatively or additionally, the queries, the patient responses and/or other information display use an auditory channel (for output and/or input).

An aspect of some preferred embodiments of the invention relates to a worn device which provides reminders to a patient, as well as querying the patient. In a preferred embodiment of the invention, the reminders include one or more of a reminder to take medicine, to eat, to drink, to be tested, to visit a doctor and/or fill out a form.

In some preferred embodiments of the invention, the device also monitors one or more physiological parameters of the patient, for example, movements, body position/posture, pulse rate, blood pressure, ECG, temperature and/or oxygenation level. Alternatively or additionally, environmental variables are monitored by the device, for example, ambient sounds, ambient temperature, ambient light levels and/or ambient air-pressure. Alternatively or additionally, to automatic monitoring, physiological parameters, ambient environmental conditions and/or patient activities may be logged manually, by a person entering them into the device. In some cases, the logging of data is initiated by a patient, in others, the device requests the data.

In a preferred embodiment of the invention, when the device queries the patient, the queries are responsive to the manually and/or automatically logged data, for example, to determine a relationship between a meal time and the effectiveness of a medicine or a side effect of the medicine. In a preferred embodiment of the invention, such querying is used during a clinical study of a medicine, to better classify, investigate and collect data about side-effects and/or medicine efficacy.

A differentiation should be noted between querying which is delayed and/or initiated responsive to a medicine taking time, expected blood level and/or other parameters which are a function of medicine metabolism and querying which delayed responsive to physiological processes, such as the circadian cycle, the menstrual cycle or the birth process.

In a preferred embodiment of the invention, an ambulatory monitor is used for one or more of disease progress monitoring, data collection for diagnosis, drug studies, drug schedule planning and/or treatment effectiveness determination. In a preferred embodiment of the invention, the data that is collected by the monitor is downloaded to a computer, on which the data may be analyzed by a technician and/or a physician.

One aspect of the invention relates to an ambulatory monitor being adapted for a particular disease. In one example, Parkinson's disease, the device may be provided with buttons having a size, shape and/or pressure response which is especially adapted for the use of Patients with Parkinson's disease. Alternatively or additionally, the logic of operation of the device is adapted to the disease, for example requiring confirmation for every input or requiring a longer press duration, to take into account a higher probability of a patient inadvertently pressing a wrong button. In another example, the monitor is adapted for pain monitoring, for example by including dedicated sensors; software for analyzing sensor results and displaying different queries and/or reminders; and/or faceplate marking.

An aspect of some preferred embodiments of the invention relates to using an ambulatory monitor for long term monitoring. In one preferred embodiment of the invention, the device monitors changes over a long period. In another example, the device provides reminders for infrequently occurring events, for example, a yearly checkup or a reminder to replace an implanted battery. In one example, suspected Alzheimer's disease is diagnosed, by periodically presenting questions to a patient, over a long period, so that degradation of mental and/or memory skills can be assessed.

An aspect of some preferred embodiments of the invention relates to coordination of an ambulatory monitor with other medical care. In one example, a reminder device which is worn by a health-care provider is synchronized with the ambulatory monitor, so that that health care

provider (for example a personal nurse) is reminded whenever the patient receives a medicine taking reminder. Thus, the patient can feel independent, while patient compliance is increased. Alternatively or additionally, one or more queries may be directed at the health-care provider, for example, to report on the patient's movements, activity state, mental alertness and/or mood. Such two coordinated monitors may also be useful where the patient does not answer queries at all, for example senile persons or babies. The two devices may be coordinated using wireless communication, for example, IR, Ultrasound or RF radiation. Alternatively or additionally, the devices are coordinated using a synchronized clock and suitable logic, so that one device is aware of the expected operation of the other device.

One aspect of some preferred embodiments of the invention relates to a method of data entry by a patient. In a preferred embodiment of the invention, the patent entered at least some of the data using an analog scale, for example, entering a pain level on a scale between 0 and 10. In a preferred embodiment of the invention, the data is entered by pressing a button to move a marker along a scale and releasing the button when the desired data value is displayed. This data entry method has the advantage of clear feedback to the patient regarding his input. In addition, if the patient has difficulty entering data, the absolute error may be expected to be small. Further, correcting such a data entry does not require erasing the data entry and reentering it, only correcting it, for example by moving the marker some more. In one embodiment of the invention, the analog scale is displayed with a varying resolution, so that there is a maximal resolution at about the marker. Alternatively or additionally, the speed of motion of the marker is a function of the duration of the button pressing. In some cases, information regarding the patient state and/or various physiological problems thereof may be determined by analyzing the act of data entry itself. Analog data entry, often provides more such data to be analyzed.

In a preferred embodiment of the invention, a patient may enter several types of data using an "analog" data input. Alternatively or additionally, some of the data entry may comprise selection from a list of discrete entries. Optionally, the physician sets the values of the ends of the analog scale and/or of the discrete choices. It is noted that using an Analog input device is known for patient studies. However, such a device is typically large (~10cm) and inconvenient to carry around. In addition, it is not practical to provide a patient with two or more such devices to entry multiple data types. Thus, comparison of changes in two such entered data types in an ambulatory patient was not a viable option.

An aspect of some preferred embodiments of the invention relates to data analysis of data acquired by the ambulatory monitor. One advantage of some monitors of the present

invention is synchronization between the patient query responses, medicine taking and other activities of the patient. In one example, a data analysis can be used to determine an average "time-to-ON" of a Parkinson's patient (i.e., the time period from the time the medication was taken until the patient switches from OFF to ON and feels an improvement in his motor abilities).

An aspect of some preferred embodiments of the invention relates to interconnecting an ambulatory monitor and external communication networks. In a preferred embodiment of the invention, the monitor can connect to a doctor's web site or to a pharmaceutical companies web site to upload patient data and/or responses to queries, and/or to download new programming, for example for detecting and/or avoiding newly discovered side effects or inter-drug interactions.

An aspect of some preferred embodiments of the invention relates to the determination of pain level from an analysis of automatically sensed movement and/or posture data. In a preferred embodiment of the invention, sudden onset of pain and/or high pain levels are identified when there is a sudden reduction in the amount of movement of an accelerometer. In another example, pain levels may be correlated with the patient's manner of walking: accelerations, gait profile, regularity of rhythm, step size, speed, way of starting and/or favoring of limbs (especially in lower back pain and limb injuries). In a preferred embodiment of the invention, the monitor learns to associate particular characteristics of features of the walk and/or movement profile with varying levels of pain. Alternatively or additionally, pain level may be determined by analyzing the temporal profile of the patient's posture and/or position, for example, walking straight, walking hunched, laying down, standing up or sleeping. Alternatively or additionally, such changes in motion are correlated with changes in a measured heart rate (which is expected to increase with pain).

There is therefore provided in accordance with a preferred embodiment of the invention, an ambulatory monitor, comprising:

a fastener for attaching said monitor to an ambulatory person to be monitored;

a display;

an input interface; and

a query generator which generates queries to said display and which receives answers to said queries using said input interface.

Preferably, the monitor comprises:

at least one sensor which generates a signal responsive to a sensed value; and

an automatic logger, which logs data responsive to said signal. Preferably, data comprises raw signal data from said sensor. Alternatively or additionally, said data comprises process signal data from said sensor. Alternatively or additionally, said at least one sensor comprises a physiologic sensor that senses a physiologic variable of said person. Alternatively or additionally, said at least one sensor comprises an environmental sensor that senses a parameter of an environment of said person. Alternatively or additionally, said at least one sensor comprises a motion sensor that senses a motion of at least of a portion of said person. Alternatively or additionally, said at least one sensor comprises a motion sensor that senses a change in posture of said person. Alternatively or additionally, said at least one sensor comprises a motion sensor that senses a change in body position of said person. Alternatively or additionally, said motion sensor comprises an accelerometer. Alternatively or additionally, said at least one sensor comprises at least two sensors, of different types. Alternatively or additionally, said at least one sensor comprises at least two sensors, which measure different parameters. Alternatively or additionally, said at least one sensor comprises at least two sensors, which are attached to different parts of said person. Alternatively or additionally, said at least one sensor comprises a sensor which is spatially separate from said monitor. Preferably, said sensor is a wireless sensor.

In a preferred embodiment of the invention, at least one of said queries is generated responsive to said logged data. Preferably, said query is generated at a delay responsive to said logged data. Preferably, said delay is responsive to a metabolism of a medication taken by said person. Alternatively or additionally, said delay is responsive to a physiological process of said person.

In a preferred embodiment of the invention, said monitor generates a medication schedule responsive to said logged data. Alternatively or additionally, said fastener comprises a wristband. Alternatively or additionally, said monitor is adapted to be worn around a neck. Alternatively or additionally, said display comprises a visual display. Alternatively or additionally, said display comprises an audio display.

In a preferred embodiment of the invention, the monitor comprises a reminder generator which provides said person with at least one reminder using said display. Preferably, said query generator generates at least one query responsive to a response of said person to said at least one reminder. Possibly, said response comprises not complying with said reminder. Alternatively or additionally, said at least one reminder comprises a reminder to eat. Alternatively or additionally, said at least one reminder comprises a reminder to drink. Alternatively or additionally, said at least one reminder comprises a reminder to take a certain

medication. Alternatively or additionally, said at least one reminder comprises a reminder for a medical checkup. Alternatively or additionally, said at least one reminder comprises a reminder for a medical test.

In a preferred embodiment of the invention, the monitor an alerter which calls attention of said person to said display.

In a preferred embodiment of the invention, said input interface is operative to receive unsolicited input from said person. Preferably, said input comprises an indication of a disease state. Alternatively or additionally, said input comprises an indication of a side effect. Alternatively or additionally, said input comprises an indication of an effect of said medicine. Alternatively or additionally, said input comprises an activity of the person. Alternatively or additionally, said query generator generates at least one query responsive to said input. Preferably, said query is generated at a delay responsive to said input. Preferably, said delay is responsive to a metabolism of a medication taken by said person. Alternatively or additionally, said delay is responsive to a physiological process of said person.

In a preferred embodiment of the invention, said monitor generates a treatment schedule responsive to said input. Preferably, said treatment schedule comprises a medication schedule.

In a preferred embodiment of the invention, said query generator generates at least one secondary query responsive to said person's response to said at least one query. Alternatively or additionally, said query generator comprises a memory and wherein said memory has stored therein an indication of at least one query directed to clinical testing of medical treatment. Alternatively or additionally, said query generator comprises a memory and wherein said memory has stored therein an indication of at least one query directed to selecting between two or more medication schedules.

In a preferred embodiment of the invention, said monitor is adapted for monitoring a particular health condition of said person. Preferably, said health condition comprises a chronic disease. Alternatively or additionally, said health condition comprises pain. Alternatively or additionally, said health condition comprises heart disease. Alternatively or additionally, said health condition comprises an anxiety disorder. Alternatively or additionally, said health condition comprises a depression disorder. Alternatively or additionally, said health condition comprises an ADD (Attention deficiency disorder). Alternatively or additionally, said health condition comprises a pulmonary difficulty. Alternatively or additionally, said health condition comprises diabetes. Alternatively or additionally, said health condition

comprises a progressive disease. Alternatively or additionally, said disease comprises Parkinson's disease. Alternatively, said health condition comprises a non-disease condition.

In a preferred embodiment of the invention, said monitor is adapted for tracking a health condition which is being modified using a medical treatment.

In a preferred embodiment of the invention, said monitor is synchronized with a second monitor, adapted to be worn by a second person and wherein said second monitor comprises an alerter which generates an alert to said second person responsive an operation at said monitor. Preferably, said operation comprises a reminder to take medicine. Alternatively or additionally, said monitor and said second monitor are synchronized using wireless communication therebetween. Alternatively or additionally, said monitor and said second monitor are synchronized using a common clock.

In a preferred embodiment of the invention, said input interface comprises at least one digital visual analog scale (DVAS) display. Preferably, said at least one DVAS comprises at least two DVASes.

In a preferred embodiment of the invention, said input interface comprises at least one menu selection interface. Alternatively or additionally, said input interface comprises an interface for entering at least two different types of data, each of said types of data having at least three possible values. Preferably, said query generator generates at least one query responsive to a relationship between said two types of entered data.

There is also provided in accordance with a preferred embodiment of the invention, a method of detecting a change in pain level, comprising:

tracking movements of at least a portion of a person; and

analyzing said tracked movements to identify changes in movement caused by a change in pain level. Preferably, said tracked movements comprises changes in posture. Alternatively or additionally, said tracked movements comprises changes in gait. Alternatively or additionally, said tracked movements comprises changes in a time profile of at least one body position.

There is also provided in accordance with a preferred embodiment of the invention, a method of data sensing, comprising:

automatically logging data of an ambulatory patient;

analyzing said data to determine at least one aspect of non-suitability of said logged data;

automatically querying said patient to provide data which improves said at least one aspect of non-suitability.

There is also provided in accordance with a preferred embodiment of the invention, a method of entering multi-state information, comprising:

displaying, on a worn device, a scale of values, including an indication of a particular value;

entering using said device a value, which entered value is indicated using said indication; and

storing said entered value, in said device, for later analysis.

Preferably, said display emulates a VAS (Visual analog scale). Alternatively or additionally, said entered value indicates a pain value. Alternatively or additionally, the method comprises repeating said displaying and said entering a plurality of times for a same type displayed scale. Alternatively or additionally, the method comprises repeating said displaying and said entering a plurality of times for a different type displayed scale.

There is also provided in accordance with a preferred embodiment of the invention, a monitor network comprising:

a first monitor, worn by a first person, which first monitor generates an alert to said first person; and

a second monitor, worn by a second person, synchronized with said first monitor, which generates an alert to said second person responsive to said first monitor. Preferably, said first and second monitors are synchronized using a common clock. Alternatively or additionally, said first and said second monitors are synchronized using at least one wireless transmission between them.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more clearly understood from the following detailed description of the preferred embodiments of the invention and from the attached drawings, in which:

Fig. 1 is a block diagram of an ambulatory monitor, in accordance with a preferred embodiment of the invention;

Fig. 2A is a schematic illustration of a faceplate of an ambulatory monitor for Parkinson's disease, in accordance with a preferred embodiment of the invention;

Fig. 2B is a schematic illustration of a faceplate of an ambulatory monitor for pain management, in accordance with a preferred embodiment of the invention;

Fig. 2C is a schematic illustration of a faceplate of an ambulatory monitor for pain management, illustrating an alternative data entry mechanism, in accordance with a preferred embodiment of the invention;

Figs. 3A and 3B comprise an exemplary data display and analysis screen for a data analysis software in accordance with a preferred embodiment of the invention;

Fig. 4 is an exemplary flowchart for a querying logic in accordance with a preferred embodiment of the invention; and

Fig. 5 is a block diagram of a networking embodiment of an ambulatory monitor in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 is a block diagram of an ambulatory monitor 20 for a patient 21, in accordance with a preferred embodiment of the invention. Typically, monitor 20 includes an alert generator 24, for alerting patient 21 and an input 28 for receiving responses from patient 21. In a preferred embodiment of the invention, monitor 20 includes a display 26 (audio, visual or both) which is used to present alerts in greater detail and/or to query the patient. Preferably, monitor 20 includes a sensor 32, for example an accelerometer, for automatically logging data about movement, physiological and/or state environment of patient 21.

In a preferred embodiment of the invention, the operation of monitor 20 is coordinated using a controller 22. Logged data is preferably stored in a memory 34, for example a solid state memory or an electro-mechanical memory such as a magnetic tape.

In a preferred embodiment of the invention, monitor 20 can communication with other devices using a communication port 30, for example to download data to a personal computer 36.

In a preferred embodiment of the invention, monitor 20 is worn like a wristwatch, and is preferably designed to look like one, to reduce patient embarrassment.

In a preferred embodiment of the invention, monitor 20 is powered using a standard-type battery. Alternatively, monitor 20 is powered using a rechargeable battery. Alternatively or additionally, monitor 20 is powered using solar power or by the inertial power (from the movement of monitor 20). Preferably, when the battery is low, monitor 20 alerts the patient to download information and/or replace or recharge the battery. Alternatively, monitor 20 shuts down less critical functions or includes a backup power source, so that power is available for critical monitoring or reminder tasks and/or maintaining the integrity of recorded data. In a preferred embodiment of the invention, controller 22 conserves power by using a lower clock rate when no processing is required, for example, as compared to a higher clock rate when real-time data analysis is required.

Alert 24 is preferably used to remind patient 21 to perform a certain action, for example, taking medicine, testing a physiological parameter (such as glucose concentration in

the blood or blood pressure), perform a certain activity (such as eat, drink or exercise), respond to a presented query and/or fill out a clinical study form. In a preferred embodiment of the invention, alert 24 is an audio alert, for example a buzz or a verbal message. Alternatively or additionally, alert 24 utilizes a flashing light. Alternatively or additionally, alert 24 uses a vibration, for example by electrifying a piezoelectric element or a solenoid on the back of monitor 20, using an AC current. Alternatively or additionally, alert 24 can drive a small current through patient 21. Alternatively or additionally, alert 24 can send a wireless signal to a free-standing alert device, for example, a desk-top buzzer. In a preferred embodiment of the invention, display 26 is used to display a message that explains the alert. Alternatively or additionally, controller 22 monitors a patient's response to the alert, to determine if the alert was received. In some embodiments of the invention (for example as described below), monitor 20 can communicate with a doctor or a health-care professional to warn that the alert was not responded to.

In a preferred embodiment of the invention, the medicine is taken by patient 21 from a separate pill-box. Alternatively or additionally, the pill-box is controlled by monitor 20 to open at the time of the alert and/or to dispense a relevant pill. Such control may be time based or may be by wireless communication between the monitor and the pill-box(es). Alternatively or additionally, monitor 20 itself includes a storage for medicine which is to be taken by the patient. Alternatively or additionally, monitor 20 directly dispenses the medicine, for example by controlling a drug pump or a electrophoresis trans-dermal drug patch. Alternatively or additionally, for example for angina patients, when a patient feels pain, he indicates the pain sensation to monitor 20, which responds by providing a suitable medication by one of the above methods.

In a preferred embodiment of the invention, patient 21 can enter data to monitor 20 using input 28. In some cases, the data entry may be in response to a reminder or a query by monitor 20. For example, in response to a reminder to take medicine, a patient will enter an indication that the medicine was taken. In other cases, the data entry may be initiated by the patient. For example, a patient may enter meal times, a sudden feeling of pain or the onset of a side effect. In general, the entered data may comprises psychological data, physiological data, environmental conditions, explanations for automatically monitored events and/or commands which affect the operation of monitor 22.

In a preferred embodiment of the invention, sensor 32 is used to automatically monitor the patient. Preferably, the raw sensor data is stored. Alternatively or additionally, the data is compressed, preferably using a loss-less compression scheme. Alternatively or additionally,

the data is analyzed before being stored to identify features and/or interesting portions thereof, which features or portions are stored. Alternatively or additionally, the data is stored using a lossy compression scheme. Memory 34 on which the data is stored is preferably integral with monitor 20. Alternatively, memory 34 may be contained in a separate package, connected by wired or wireless communication means to monitor 20. In a preferred embodiment of the invention, the analysis and/or recording of sensor data for storage and/or feature extraction is responsive to previously acquired data, data entered by the patient and/or data which should have been entered by the patient but was not.

Alternatively or additionally, the acquisition of sensor data is made responsive to previously acquired data and/or data entered by a patient. In one example, data is logged only for times which appear to be relevant, for example, based on previously determined schedules and/or responsive to an event. In another example, gain, level and/or other characteristics of a sensors may be adjusted so that the sensor is optimally configured to sense expected data values. For example, a sensor may be configured to better detect tremors or to better detect gross movements, by modifying the sensor's gain..

In a preferred embodiment of the invention, data is downloaded from monitor 20 to computer 34. Alternatively or additionally, programming is uploaded from computer 34 to monitor 20. Alternatively or additionally, data, especially data useful for internal algorithms, may be uploaded from computer 34 to monitor 20.

In a preferred embodiment of the invention, the connection between communication port 30 and computer 34 uses standard networking hardware, for example, IR or RF networking or a serial cable. Alternatively, a dedicated communication protocol is used. Alternatively or additionally, port 30 is adapted to connect using an analog telephone line, the port possibly incorporating a modem. Possibly, port 30 is operative to generate an Internet connection, for example to a doctor's Web site. In some cases, port 30 may connect to a patient's personal computer which, itself connects to an Internet. Preferably, a special program is executed on the personal computer to communicate with the web site and/or to program the monitor. Possibly, the program may serve as an enhanced user interface to the monitor, for example to enter "requests" or to program in reminders, even when the personal computer is not connected to an Internet. Optionally, the program itself may be downloaded from the web site, for example as a Java applet. Possibly, the monitor itself is programmed in Java, so that it can be readily reprogrammed, e.g., from the Internet. In a preferred embodiment of the invention, the web site is that of a pharmaceutical company or of the manufacturer of the

monitor, thus allowing a patient to receive updates, for example, regarding his medicine, novel side effects and/or dosage limitations, in a direct manner.

Fig. 2A is a schematic illustration of a faceplate 40 of an ambulatory monitor for Parkinson's disease, in accordance with a preferred embodiment of the invention. In the exemplary embodiment shown, the monitor includes one or more band holders 42 for attaching a wristband to the monitor. Faceplate 40 preferably comprises a display 44, for example a dot-matrix LCD display, which can be used to display numbers (e.g., the time), short textual messages, icons, pictures, diagrams, symbols and/or images. A button 46 is used to indicate taking a meal. A button 48 is used to indicate taking of a medicine. In a preferred embodiment of the invention, monitor 20 generates an alert when it is time to take medicine, possibly also flashing a LED at or near the "medicine" button. When patient 21 takes the medicine, he presses the button and the flashing stops. Alternatively, in some cases the patient takes the medicine on his own and indicates this to the monitor, which then reschedules reminders for taking medicine.

A button 50 is used to indicate sleep and wake times. Buttons 52, 54 and 56 are preferably used to indicate a state of the Parkinson's disease, with button 54 allowing a patient to indicate an "OFF" state, button 56 allowing a patient to indicate an "ON" state and button 52 allowing the patient to indicate a state of dyskinesia. These indications may be additional or alternative to an automatic detection of these states by monitor 20, by analyzing reading from sensor 32. Preferably, these indications are used by monitor 20 to calibrate ranges for parameters which are associated with these disease conditions. Alternatively or additionally, monitor 20 learns to associate particular movement frequencies and/or other features of the sensor data with particular disease states, for example, for a particular patient, an "OFF" state may be characterized by a sudden, short, increase in motion in a particular frequency band, followed by a general depression of motion in all frequency bands. In a preferred embodiment of the invention, a "query" to a patient may consist of flashing LEDs (not shown) at or near the relevant buttons (e.g., one or more of ON, OFF, meal, sleep/wake, Dyskinesia and medicine). The patient responds to the query by pressing on one of the flashing buttons.

Two additional buttons 58 and 60 may be used for programming the monitor. In a preferred embodiment of the invention, an undo button 57 is provided to undo erroneous data entry.

In a preferred embodiment of the invention, all the buttons used share a similar logic and are activated by a single press. Alternatively, more complex and/or different logics may be used, for example to allow entry of more complex data or to better suit the special

circumstances of patient's having Parkinson's disease. In one example, a button-press may be accepted only if it was pressed for at least a predetermined threshold duration. In another example, every button press may require an acknowledgment, for example using a different button. In another example, only the relevant buttons are available for receiving input, for example, responsive to a current state of the monitor, patient input, sensor data or an outstanding alert. Alternatively or additionally, data entry may utilize speech recognition, preferably user dependent speech recognition, with a patient's speech pattern being uploaded using port 30. In some embodiments, data entry may use both speech (for the entry) and buttons (for the confirmation). Alternatively or additionally, speech sounds can be used for confirmation, for example, to confirm taking of medication, in response to a query.

In another example of a button logic one press on a button displays its state and a second press is required to change the state.

In a preferred embodiment of the invention, monitor 20 includes special logic that is specific for Parkinson's disease. Such logic is preferably dedicated to the disease process of Parkinson's and/or to the effects and/or side effects of particular medication. In one example, monitor 20 changes the schedule of medicine taking responsive to reported side effects or in order to correlate the "ON" state with the times at which a patient needs activity, for example, a physical therapy meeting. Thus, a patient and/or a doctor may be able to enter "requests" into monitor 20, either directly into the monitor or using programming from a computer. Such requests and/or other optimization aims may also be preprogrammed in to monitor 20. In a preferred embodiment of the invention, one or more of several variables are under control of the monitor to achieve such optimization, including: dosage, medication time, medication scheduling, temporal relationship between medication, meals, activities and/or other medical activities, such as physical therapy meetings.

In another example, monitor 20 determines if certain side effects are too severe or indicate a critical adverse reaction to a medication. In many cases, monitor 20 cannot make these determinations solely using logic and may thus query the patient for missing information. Alternatively, monitor 20 may request patient 21 to ask a doctor certain questions, report information and/or to connect the monitor to a communication line, for example, so the monitor can be updated and/or report to a supervising physician.

In a preferred embodiment of the invention, a severity of a side effect medicine efficacy and/or other "analog" information is entered using a DVAS (Digital Visual Analog Scale). In a standard VAS, a ruler with a (mechanically) movable marker is provided to the patient. The ruler shows a scale, for example, pain, and the marker is used to subjectively

select a pain level. Such a ruler is very bulky and usually does not automatically record data. Thus, patient compliance is a problem and using two such VASes is not practical. In a DVAS, the "VAS" is always available (e.g., on the wrist) and any number of DVASes can be programmed into a single monitor, so several variables may be entered using visual analog scales. Further, it is possible to visually and/or automatically compare the values entered on the several scales and/or data entered using other types of data input. A differentiated should be noted between entering "analog" data for data entry and entering data to set a control variable.

In a preferred embodiment of the invention, the data is displayed as a bar (filling an entire side of the display or only at the marker position) in a range of values. Such an indication can easily be corrected by moving the bar left or right. Further, it is possibly for the patient to control the resolution of his reply. For example, when in extreme pain, a patient may be satisfied with entering a large value (to indicate great pain), without taking the time to enter an exact value. In some embodiments of the invention, a rotatable control is provided to enter DVAS data, in others, a pair of buttons is designated {"Up", "Down"}.

Fig. 2B illustrates a faceplate 62 for a pain management application, using a DVAS for inputting pain severity. In this example, the DVAS comprises a lit triangle, with its apex at the "low" side and its base at the "high" side. Thus, although the horizontal dimension of the DVAS is reduced relative to that of a standard VAS, an added dimension, e.g., a vertical dimension, can partly or completely compensate for any loss in discernability. Alternatively or additionally, to shape, the DVAS may also be color encoded, for example, blue to red (e.g., blue = OK, red = severe pain).

Fig. 2C illustrates a faceplate 64 for a pain management application, wherein, pressing a button shows a menu (rolling) on the display, items from which menu are selected using the same or other buttons. In some embodiments, a menu may also include sub menus. Reference 66 indicates a complete list of possible selections in this menu.

In a preferred embodiment of the invention, the doctor can set up (using the communication port) the scale and/or format of the DVAS. Alternatively or additionally, the doctor can setup queries which are responsive to relationships between data entered using the DVASes and/or historical data.

In another example of a DVAS related query and/or activity, a doctor and/or patient can pre-set a goal, for example, a pain level. Once that pain level is reached, the medication may be stopped, switched with another medication and/or its schedule changed. In some cases,

an exact determination of a pain level may require querying the patient for more details, after he enters a VAS value.

As mentioned above, display 44 may be used for displaying one or more of queries, reminders, alerts and data input. Alternatively or additionally, display 44 is used for displaying a DVAS. Alternatively or additionally, display 44 may be used for graphically displaying logged data, for example data entered by a user or data which is automatically logged. In a preferred embodiment of the invention, such data is displayed textually and/or graphically, especially if showing a history of a variable, for example, variations of a pain level over time. Alternatively or additionally, display 44 may be used to display processed data and/or an analysis of data, for example in response to a patient request. Alternatively or additionally, display 44 may be used to provide the patient with instructions (visual and/or audio) on medication, healthful activities and/or using the monitor. Such instructions may be requested by the patient. Alternatively or additionally, such instructions are automatically generated when it is determined that the patient is not using the monitor in a correct fashion and/or is not using it enough.

Figs. 3A and 3B comprise an exemplary data display and analysis screen 70 for data analysis software in accordance with a preferred embodiment of the invention. As mentioned above, raw data and/or possibly partially analyzed data is preferably downloaded to a personal computer, on which a physician can perform additional analysis. In an exemplary embodiment, such analysis may include a display 72 showing ON and OFF state times, times medications were scheduled to be taken and time sat which medications were actually taken. A display 74 shown the ON duration as a percentage of waking hours. A display 76 shows the time to achieve an ON state after taking the first medication dose in the morning. A display 78 and a display 80 correspond to displays 74 and 76, but show long-term information, for example, monthly information. It is noted that the provision of better correlation between the sensor data, patient activities and/or patient reporting allows a better analysis of the data and confirms the usage of graphical display.

In a preferred embodiment of the invention, the data analysis program may initiate actions responsive to the downloaded data and/or its analysis, for example, to page a doctor or to send him e-mail. the conditions for performing such activities may be pre-set. Alternatively, the doctor may program them in, for example, via his Web site.

In other preferred embodiments of the invention, additional or alternative data processing techniques may be used. Preferably, data from monitor 20 and/or from the PC

processing program may be converted to a standard file format to be analyzed by standardized data processing programs, for example Excel or SAS.

One aspect of some preferred embodiments of the invention is scheduling of reminders and/or of queries. In a preferred embodiment of the invention, the scheduling can be a function of data which is entered by the user or analysis of automatically logged data, as well as a function of preset time and date schedules. As indicated above, scheduling and/or dosage of medicine taking can be preset or it can be a function of the effect and/or side effects that the medicine(s) (one or more types) is causing. The effects and/or side effects may be automatically detected, may be entered by a user or may be determined by correlating the user-entered information with the automatically sensed information.

In a preferred embodiment of the invention, queries may be scheduled to be at a preset time, for example, every 4 hours or every two days. Alternatively or additionally, queries may be scheduled to be delayed relative to events, for example one hour after eating or 15 minutes after achieving an ON state. In addition, more complex dependencies may be created, for example, 10 minutes after achieving an ON state if medication A was taken or 20 minutes after the ON state if medication B was taken. Possibly, a script programming language is provided for the physician to program when and under what circumstances queries are presented. Alternatively or additionally, a state machine representation may be provided, with certain states generating particular queries and certain responses (or monitored data) generating transitions to particular states.

Alternatively or additionally to queries being generated responsive to patient responses, a particular series of queries may be designed for particular situations, to better direct the queries to a patient. For example, if a patient enters that he has felt a side effect, a series of queries may be asked to determine the type, extent and/or other properties of the side effect. In addition, in some embodiments of the invention, data input to the monitor is limited so substantially only yes/no questions can be asked, requiring more questions to get the required information. The "tree" of questions may be dependent on the patient state, for example, with questions about fever being asked earlier on for medication A than for medication B. Additionally, a patient response or input may cause the scheduling of future questions. For example, if a patient complains about a headache, a follow-up question about the headache may be asked 1 hour later. Alternatively, a patient may be reminded in one hour to report again on side effects. Queries may also be used to present instructions to a patient, for example, to take aspirin for a headache or to see a doctor at once.

The scheduling of some events may be set to be at a delay after a different event (e.g., one hour after eating). In a preferred embodiment of the invention, one or more of three types of delays are provided: (a) simple time delays; (b) metabolic-related delays; and (c) physiologic process related delays. Metabolic related delays, which are responsive to the metabolizing of the medication by the patient, are typically used to make sure that a patient acts or is queried at a time when the effect of the medicine is expected to be maximal, minimal or at a steady state. Physiologic process related delays, which are responsive to the operation of the patient's body, are typically used to match the querying to what the patient's body is doing or is supposed to be doing. Examples of relevant physiologic processes (not only for Parkinson's) include, inflammation response, temperature adaptation, circadian rhythm, menstrual cycle and gestation process. Parameters of the metabolic process and of the physiological processes are typically patient dependent values which must be loaded for each patient. In some cases, an average value or a group value (e.g., based on age) may be sufficient.

Fig. 4 is an exemplary flowchart for a querying logic in accordance with a preferred embodiment of the invention. As can be appreciated, other flowcharts may be used for other embodiments of the invention. further, an particular flowchart may be individually tailored, for example, per patient, per disease and/or pre medication. In this example, a patient is reminded to take medication at 15:00. The medication may have a side effect of a headache, after it is absorbed by the body. In the sample flowchart, a patient is reminded to take the medicine if he did not indicate he had taken it. If he complains of no headaches or other side effects, an increase in dosage is considered (possibly dependent on the existing dosage not being effective enough, no reports of side effects over a period of time and a doctors agreement in advance). If there are persistent side effects, the dosage may be automatically reduced.

In a preferred embodiment of the invention, monitor 20 includes self testing and safety capabilities, for example, to determine if the sensors, memory and/or controller are working properly. Additionally or alternatively, the monitor checks that the patient behavior is within certain bounds, for example, that his movements are normal or that he is reasonably punctual with respect to medicine taking.

In a preferred embodiment of the invention, the logic of the monitor instigates actions, for example, suggesting to a patient that he call a doctor 20 if the duration of OFF states is increasing. Additionally or alternatively, the monitor may turn itself off, if it malfunctions. Additionally or alternatively, the monitor may initiate a call for help, for example if monitor 20 includes a wireless communication means.

In a preferred embodiment of the invention, the monitor logic includes a series of conditions, each of which, if met, may indicate a malfunction or problem of some sort. Additionally or alternatively, at least in some operational states, the monitor includes one or more functions which check correlation between data and/or analysis sources, for unreasonable discrepancies. In one example, the monitor checks for a significant discrepancy between disease states as inputted by a patient, for example an OFF state and movement detected by sensor 32 during the alleged OFF state. Additionally or alternatively, in monitors with two or more sensors, the outputs of the sensors may be cross-correlated.

In a preferred embodiment of the invention, the monitor includes one or more models of how the patient and/or medicine are expected to perform. In some preferred embodiments of the invention, these models may be used for planing medication and/or treatment schedules and/or presenting predictions to the patient. These models may be embodied using a neural network or using a state machine model. In one example, the monitor may generate an alert if a patient did not perform an expected activity, such as eat supper. The monitor will preferably alert the patient and ask if a data entry was missed. In another example, if a dose of medicine has no effect, the monitor will ask the patient if perhaps the medicine was not taken.

In a preferred embodiment of the invention, the model(s) are pre-set and/or programmed into the monitor, during a programming session. Additionally or alternatively, the model(s) for a particular patient and/or medicine regimen may be learned, for example, if they are embodied using a neural network or by learning parameters for a pre-set model. In one example, a model may model daily, weekly, monthly or yearly schedules of the patient and/or of his environment.

In a preferred embodiment of the invention, the monitor is used to track the effectiveness of certain medicines, for a particular patient. Possibly, a doctor can program such a monitor to alternate between different schedules so that the doctor can assess which schedule and/or medication has the best effect and/or the least side effects. Further, in some preferred embodiments of the invention, the monitor is used for clinical testing of drugs. As can be appreciated the automatic scheduling of queries and/or the dependency of some queries on logged data can be used to better determine side-effects and/or their causes and/or other parameters. Thus, a clinical study can obtain more effective information from the same number of test subjects, possibly in less time. Further, by correlating manual and automatic data entry, a higher confidence level in the data may be achieved.

Fig. 5 is a block diagram of a network embodiment of an ambulatory monitor in accordance with a preferred embodiment of the invention. A patient monitor 90 is preferably

networked with a health care provider monitor 92 and/or a base station 94. The network may be a real-time network, in which messages are transmitted in real-time between the elements of Fig. 5. In some embodiments base station 94 is required as a go between, in some embodiments base station 94 is used for back up or for remote reporting and in some cases no base station 94 is provided. Additionally or alternatively, the network may be an off-line network, in which synchronization is achieved by the elements sharing a common clock and being aware of the logic of the other elements. In this case, the monitors may be synchronized with each other periodically, possibly using base station 94 to perform the synchronization. In some cases, base station 94 (or monitor 92) may be utilized to perform some or all of the processing and/or data store for monitor 90. Preferably however, monitor 90 includes at least a limited storage and/or processing capability for when it is out of range of the base station.

In a preferred embodiment of the invention, a patient with a monitor 90 may not be trusted to comply with the instructions he receives from the monitor and/or to correctly (or at all) answer queries from the monitor. However, such a patient may still require a sense of autonomy, for example if the patient has "bad" days and "good" days. In a preferred embodiment of the invention, a monitor 92 is worn by the patient's health care provider (e.g., a live-in nurse). When the patient is reminded to take medication, the nurse is preferably also alerted, to check if the patient is complying. Additionally or alternatively, if the patient does not indicate that he has taken the medicine, it may be the nurse's monitor which sounds an alert, not the patient's (since he has already shown non-compliance). In some cases, a person other than the patient may respond to the alerts on the patient's monitor. In some cases, monitor 92 may be placed at a nurses station in a hospital.

In some embodiments of the invention, base station 94, patient monitor 90 and/or health care provider monitor 92 may be connected to a larger network, for example a hospital information center 96. Alternatively or additionally, they may be connected to a drug company center 98. Preferably, such complex network topologies utilize an Internet or direct dial-up, however, other available networking solutions may be used. In a preferred embodiment of the invention, patient monitor 90 uploads information to the hospital information system, to aid in diagnosis of the patient. Alternatively or additionally, the monitor downloads clinical information to be stored on monitor 90 or the patient's PC, to be used in programming the device, analyzing its results or for emergency healthcare providers. Preferably, the monitor includes a simple interface (for example a button and speech output) to allow an emergency medical practitioner to retrieve critical information (e.g., drugs ingested) from the patient.

The above description has focused mainly on using a monitor for Parkinson's disease. However, such a monitor may be useful for tracking other chronic conditions.

In one example, a pain monitor is provided, to monitor the changes in pain during the day and to aid in deciding on a suitable pain-reliever schedule. Alternatively, the monitor may be programmed to decide on a schedule. In a preferred embodiment of the invention, onset of pain may be automatically detected, by detecting changes in motion of the patient. In a preferred embodiment of the invention, one or more additional sensor may be provided, to back up the movement sensor, for example a heart rate sensor may be used to detect an increased heart rate on the onset of pain.

Alternatively or additionally, a pain level may be detected by analyzing characteristics of a patient's gait. For example, a correlation may be expected between step size, speed and/or accelerations, depending on the pain level. In particular, if the pain is affected by the walking, for example, back pain, leg pain or arm pain, it may be expected that one side of the body be favored, causing a marked effect on the rhythm of walking. Alternatively or additionally, the time spent in different postures may change, for example, more time standing or laying down (when in pain) and less time sitting. In some embodiments, a plurality of sensors may be provided on the body, to differentiate between the different postures (e.g., sitting is like standing, except for the knee-shoulder distance). Alternatively or additionally, one or more of the sensors may sense angle, relative or absolute position and/or velocity, rather than acceleration.

In a preferred embodiment of the invention, the monitor (and/or the data analysis programs on the personal computer) learns to associate certain features of the movements and/or postures with certain pain levels (or other disease states and/or symptoms). Preferably, this learning is accelerated by the patient entering a subjective input regarding the pain state. Preferably, the association is performed by the monitor. Alternatively or additionally, the association is performed by the patient's (or the doctor or drug company) computer, by analyzing data downloaded to it from the monitor.

Fib. 2B and 2C, referred to above, illustrate faceplates for a pain management application, in which buttons 50 and 46 are marked "down" and "up" respectively, buttons 48 and 52 are marked "sleep/wake" and "activity" respectively and buttons 54 and 46 are marked "medicine 1" and "medicine 2" respectively.

In a preferred embodiment of the invention, the monitor may include a microphone to detect ambient sounds. These sounds may be correlated with the patient's activities, for example, loud sounds may appear right before acceleration (subway). In another example,

these sounds may originate from the patient himself, for example coughing, sneezing and snoring, which activities it may be desired to monitor. This is another example where a person other than the wearer of the monitor may use the monitor to enter data (the patient's bed partner who is woken by the snoring). Sound analysis may be performed on-line or off-line, using automated processing and/or using a human operator.

In another preferred embodiment of the invention, a gastro-intestinal disease management monitor is provided, to track gastric reflux, irritable bowel syndrome, chronic constipation or diarrhea and/or other GI ailments. Preferably, an acoustic sensor is used to detect loud bowel sounds that travel through the body. In this context it is noted that, many bowel activities have a natural rhythm of, for example 20 minutes, to which the monitor is preferably attuned. Alternatively or additionally, a patient may enter an indication of a burning sensation. Alternatively or additionally, the monitor may query the patient at preset (or learned) times after the meal to see if any symptoms are being felt. Preferably, monitor 20 learns patterns of symptoms with and/or without medication, so that the queries are better timed to coincidence with the onset and/or decline of the symptoms.

Such a monitor as described herein above may also be used for other health-related applications. One advantage of some of the embodiments described herein, which advantage is useful for other health applications, is that the patient himself can be queried to supply missing, ambiguous and/or undetectable information. Thus, an ambulatory monitor can be used even if a sensor cannot guarantee high quality and/or complete information.

In one example, an ambulatory monitor is used to track hyperactivity and ADD (attention deficiency disorder) in children. A typically relevant sensor is an accelerometer, to determine the amount of movement and/or fidgeting. In order to differentiate between game playing and hyperactivity-related fidgeting. The child may be queried, for example as to whether he is playing a game (where movement is expected) or if he is at a lesson (where movement is not expected). Alternatively or additionally, a child can be queried directly or indirectly (using a simple test) to determine his attention span. In younger children, it may be advantageous to use icons or pictures, rather than textual messages.

Other examples of psychiatric disorders, such as anxiety and depression/mania are also characterized by significant swings in activity levels, body postures, shaking and/or other easily measured parameters. In addition, by querying the patient (or applying one or more psychiatric evaluation questions) it is possible to "measure" the mood of the patient. Thus, the efficiency of drugs, their interactions with events in the patient's life and/or the best timing for dispensing, may be determined with the help of an ambulatory monitor. Also, in an anxiety

embodiment, it may be advantageous to query the patient after an anxiety attack and medication taking, to determine the exact effect of medication. Preferably a scale having between 3-5 degrees of anxiety and/or a DVAS are used to input the anxiety level. The patient preferably reports the cause of the attach by selecting from a preset list of options. Possibly, if the cause is not on the list, the patient enters the cause using a voice recording and/or by selecting an option marked "other". Preferably, the doctor and/or patient will reprogram the monitor to include the missing cause(s).

An ambulatory monitor may be used for incontinence, for example for a patient to report incontinence events and their (possible) causes. Alternatively or additionally, the monitor may include a sensor, for example an implanted intra-bladder or intra-abdomen pressure sensor, to sense changes in pressure which might be related to incontinence. Alternatively or additionally, a sound sensor may be used to identify coughing. Alternatively or additionally, an accelerometer may be used to identify jumping and/or other potential incontinence causing events. Possibly, when such an even is detected, a patient may be queried whether there was an incontinence event and/or reminded to perform certain exercises to avoid such events.

In a blood-pressure embodiment, the monitor may periodically measure the patient's blood pressure and/or request the patient to measure his blood pressure. Possibly, such a monitor may also record movements and/or a heart rate, to detect blood-pressure affecting event. Alternatively or additionally, the monitor may query the patient when an increase in blood pressure is detected, for the reason.

In a pulmonary embodiment (e.g., emphysema, asthma) the monitor may include a sensor for example an electrical impedance sensor or an EMG sensor to detect breathing. Alternatively or additionally, the monitor may include an oxygenation sensor to detect actual blood oxygen level. Alternatively or additionally, the monitor may include a heart-rate sensor or an accelerometer to detect movements. Possibly, the monitor may periodically (or responsive to measured parameters) request that the patient use a spiro-graph to measure lung capacity and/or other pulmonary variables. Queries may be used to help the monitor differentiate between different activities and/or to better track the onset, decline and/or duration of breathing difficulty and/or the effect of medication or exercise.

In a diabetes example, a monitor may remind a patient to test his blood sugar and/or the monitor may control an insulin pump. Alternatively or additionally, the monitor tracks sweating, heart rate, dizziness (using an accelerometer) and/or other parameters, to detect

hypoglycemia. Preferably, the patient reports when he takes food and/or insulin, and the type of food or insulin taken.

In a heart disease example, the monitor can be used to detect ECG, while the patient is queried whether he feels an arrhythmia and/or its effects which is provisionally detected by the monitor.

Additionally or alternatively, such a monitor may be used to track disease (or health) states which have a known progression and/or a hoped-for effect of medication of other treatment. In one example, a monitor may be used to track the sensations of a cancer patient undergoing chemotherapy and/or radiation treatments. In an opposite example, a monitor may be provided to track a human gestation, for example to track embryonic movements and the activity of the mother. In a preferred embodiment of the invention, embryonic movements are detected by a pressure wave caused by the movement of the embryo and propagated through the body. It should be noted that some of the applications described herein can tolerate higher noise levels than is common in other medical applications. One possible reason is that in long term monitoring the statistical data may be more important than any single datum. Another possible reason is the ability to average very long runs of data. Another possible reason is the ability to correlate between sensors and between a sensor and a patient subjective input. Additionally or alternatively, a sensor, for example a Doppler sensor may be provided on the abdomen of the mother or inside the uterus or the vagina. Such a sensor may communicate by wire or wireless with the monitor. Additionally, other of the embodiments described herein may utilize a sensor additional or alternative to the accelerometer in the monitor, for example, a temperature sensor, a blood pressure sensor and an ECG sensor. Such a sensor may be connected by wired or wireless means to the monitor.

In another example a monitor is used to track the onset and/or progression of menopause, especially in order to control the side effects caused by hormonal medication. Preferably, a more exact dosage and/or schedule of dosing may be determined by analyzing the automatically logged and/or manually entered information. Alternatively or additionally, the dosage is determined responses to queries, which queries are used to asses the effect of medication.

In a preferred embodiment of the invention, the monitor is used to provide support to a patient experiencing a new condition. For example, a patient who is newly diagnosed with diabetes is not as experienced with the diabetic lifestyle. A worn monitor may assist such a patient in acclimating to the newly required lifestyle, while minimizing unhealthy mistakes. The assistance may include periodic queries regarding well being (to detect hypoglycemia) and

reminders after meals to take insulin. In another example, a leprosy patient (which are thankfully rare today) must perform a periodic scan of his extremities to insure that he has not incurred new damage, as the nerve endings are damaged by the disease. Preferably, the level of assistance changes in time, to reflect the knowledge gained by the patient and to reduce the annoyance caused by the monitor asking too many questions. A similar reducing level of assistance may be provided for instructions regarding using the monitor. As the user becomes more proficient, such instructions should cease.

In some embodiments, reminders may be for activities other than medication, for example, a reminder to eat, drink, get up (to avoid blood clots) and/or exercise. Additionally or alternatively, the reminders may be for long-term activities, for example monthly or yearly check-ups or calibration of the monitor.

The present invention has been described with reference to medical applications, where the need for precise information, patient feedback and/or patient compliance is especially critical, more so, when taking into account that the users are often ill and/or otherwise problematic. However, it is anticipated that such a monitor may be reprogrammed for other, non-medical applications. Thus, a dedicated electronic diary with a query mechanism may be provided. In one example, such a monitor may be used by an athlete on a tight training regimen. In another example, such a monitor may be worn by data samplers (for example for efficiency studies in industrial engineering) or by service providers, to remind them or activities they must perform and/or to query them. Possibly, at least some of the queries and/or reminders may be download in real-time from a controlling device, for example a base station which is in wireless communication with all the end stations and which may also be used to perform some or all of the processing and/or data storage.

In some application, such a monitor as described above may form a software component of a more complex electronic device which is worn, for example a cellular telephone or a wrist computer. In other applications, a multi-option monitor may be provided, which monitor can be used to track several disease states. Alternatively or additionally, such a monitor is adapted to a particular disease by programming. Possibly, the buttons include programmable displays, which display their function. Alternatively, a plurality of stickers are provided which may be pasted over or at the buttons to describe their function.

It will be appreciated that the above described apparatus and methods of ambulatory monitoring may be varied in many ways. In addition, a multiplicity of various features, both of methods and of devices, has been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a

particular embodiment are necessary in every similar preferred embodiment of the invention. Further, combinations of the above features are also considered to be within the scope of some preferred embodiments of the invention. It should also be appreciated that many of the embodiments are described only as methods or only as apparatus. In addition, the scope of the invention includes methods of using, constructing, calibrating and/or maintaining the apparatus described herein. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like mean "including but not limited to".

CLAIMS

1. An ambulatory monitor, comprising:

a fastener for attaching said monitor to an ambulatory person to be monitored;

a display;

an input interface; and

a query generator which generates queries to said display and which receives responses to said queries using said input interface.

2. A monitor according to claim 1, comprising:

at least one sensor which generates a signal responsive to a sensed value; and

an automatic logger, which logs data responsive to said signal.

3. A monitor according to claim 2, wherein said data comprises raw signal data from said sensor.

4. A monitor according to claim 2, wherein said data comprises process signal data from said sensor.

5. A monitor according to claim 2, wherein said at least one sensor comprises a physiologic sensor that senses a physiologic variable of said person.

6. A monitor according to claim 2, wherein said at least one sensor comprises an environmental sensor that senses a parameter of an environment of said person.

7. A monitor according to claim 2, wherein said at least one sensor comprises a motion sensor that senses a motion of at least a portion of said person.

8. A monitor according to claim 2, wherein said at least one sensor comprises a motion sensor that senses a change in posture of said person.

9. A monitor according to claim 2, wherein said at least one sensor comprises a motion sensor that senses a change in body position of said person.

10. A monitor according to claim 7, wherein said motion sensor comprises an accelerometer.

11. A monitor according to claim 2, wherein said at least one sensor comprises at least two sensors, of different types.

12. A monitor according to claim 2, wherein said at least one sensor comprises at least two sensors, which measure different parameters.

13. A monitor according to claim 2 wherein said at least one sensor comprises at least two sensors, which are attached to different parts of said person.

14. A monitor according to claim 2 wherein said at least one sensor comprises a sensor which is spatially separate from said monitor.

15. A monitor according to claim 14, wherein said sensor is a wireless sensor.

16. A monitor according to claim 2, wherein at least one of said queries is generated responsive to said logged data.

17. A monitor according to claim 16, wherein said at least one query is generated at a delay responsive to said logged data.

18. A monitor according to claim 17, wherein said delay is responsive to a metabolism of a medication taken by said person.

19. A monitor according to claim 17, wherein said delay is responsive to a physiological process of said person.

20. A monitor according to claim 2, wherein said monitor generates a medication schedule responsive to said logged data.

21. A monitor according to claim 1, wherein said fastener comprises a wristband.

22. A monitor according to claim 1, wherein said monitor is adapted to be worn around a neck.

23. A monitor according to claim 1, wherein said display comprises a visual display.

24. A monitor according to claim 1, wherein said display comprises an audio display.

25. A monitor according to any of claims 1-24, comprising a reminder generator which provides said person with at least one reminder using said display.

26. A monitor according to claim 25, wherein said query generator generates at least one query responsive to a response of said person to said at least one reminder.

27. A monitor according to claim 26, wherein said response comprises not complying with said reminder.

28. A monitor according to claim 25, wherein said at least one reminder comprises a reminder to eat.

29. A monitor according to claim 25, wherein said at least one reminder comprises a reminder to drink.

30. A monitor according to claim 25, wherein said at least one reminder comprises a reminder to take a certain medication.

31. A monitor according to claim 25, wherein said at least one reminder comprises a reminder for a medical checkup.

32. A monitor according to claim 25, wherein said at least one reminder comprises a reminder for a medical test.

33. A monitor according to any of claims 1-24, comprising an alerter which calls attention of said person to said display.

34. A monitor according to any of claims 1-24, wherein said input interface is operative to receive unsolicited input from said person.

35. A monitor according to claim 34, wherein said input comprises an indication of a disease state.

36. A monitor according to claim 34, wherein said input comprises an indication of a side effect.

37. A monitor according to claim 34, wherein said input comprises an indication of an effect of said medicine.

38. A monitor according to claim 34, wherein said input comprises an indication of an activity of the person.

39. A monitor according to claim 34, wherein said query generator generates at least one query responsive to said input.

40. A monitor according to claim 39, wherein said query is generated at a delay responsive to said input.

41. A monitor according to claim 40, wherein said delay is responsive to a metabolism of a medication taken by said person.

42. A monitor according to claim 40, wherein said delay is responsive to a physiological process of said person.

43. A monitor according to claim 34, wherein said monitor generates a treatment schedule responsive to said input.

44. A monitor according to claim 43, wherein said treatment schedule comprises a medication schedule.

45. A monitor according to any of claims 1-24, wherein said query generator generates at least one secondary query responsive to a person's response to at least one of said queries.

46. A monitor according to any of claims 1-24, wherein said query generator comprises a memory and wherein said memory has stored therein an indication of at least one query directed to clinical testing of medical treatment.

47. A monitor according to any of claims 1-24, wherein said query generator comprises a memory and wherein said memory has stored therein an indication of at least one query directed to selecting between two or more medication schedules.

48. A monitor according to any of claims 1-24, wherein said monitor is adapted for monitoring a particular health condition of said person.

49. A monitor according to claim 48, wherein said health condition comprises a chronic disease.

50. A monitor according to claim 48, wherein said health condition comprises pain.

51. A monitor according to claim 48, wherein said health condition comprises heart disease.

52. A monitor according to claim 48, wherein said health condition comprises an anxiety disorder.

53. A monitor according to claim 48, wherein said health condition comprises a depression disorder.

54. A monitor according to claim 48, wherein said health condition comprises an ADD (Attention Deficiency Disorder) condition.

55. A monitor according to claim 48, wherein said health condition comprises a pulmonary difficulty condition.

56. A monitor according to claim 48, wherein said health condition comprises diabetes.

57. A monitor according to claim 48, wherein said health condition comprises a progressive disease.

58. A monitor according to claim 57, wherein said disease comprises Parkinson's disease.

59. A monitor according to claim 48, wherein said health condition comprises a non-disease condition.

60. A monitor according to claim 48, wherein said monitor is adapted for tracking a health condition which is being modified using a medical treatment.

61. A monitor according to any of claims 1-24, wherein said monitor is synchronized with a second monitor, adapted to be worn by a second person and wherein said second monitor comprises an alerter which generates an alert to said second person, responsive to an operation at said monitor.

62. A monitor according to claim 61, wherein said operation comprises a reminder to take medicine.

63. A monitor according to claim 61, wherein said monitor and said second monitor are synchronized using wireless transmission therebetween.

64. A monitor according to claim 61, wherein said monitor and said second monitor are synchronized using a common clock.

65. A monitor according to any of claims 1-24, wherein said input interface comprises at least one digital visual analog scale (DVAS) display.

66. A monitor according to claim 65, wherein said at least one DVAS display comprises at least two DVAS displays.

67. A monitor according to any of claims 1-24, wherein said input interface comprises at least one menu selection interface.

68. A monitor according to any of claims 1-24, wherein said input interface comprises an interface for entering at least two different types of data, each of said types of data having at least three possible values.

69. A monitor according to claim 68, wherein said query generator generates at least one query responsive to a relationship between said two types of entered data.

70. A method of detecting a change in pain level, comprising:

tracking movements of at least a portion of a person; and

analyzing said tracked movements to identify changes in movement caused by a change in pain level.

71. A method according to claim 70, wherein said tracked movements comprise changes in posture.

72. A method according to claim 70, wherein said tracked movements comprise changes in gait.

73. A method according to claim 70, wherein said tracked movements comprise changes in a time profile of at least one body position.

74. A method of data sensing, comprising:

automatically logging data of an ambulatory patient;

analyzing said data to determine at least one aspect of non-suitability of said logged data;

automatically querying said patient to provide data which improves said at least one aspect of non-suitability.

75. A method of entering multi-state information, comprising:

displaying, on a donned device, a scale of values, including an indication of a particular value;

entering, using said device, a value, which entered value is indicated using said indication; and

storing said entered value, in said device, for later analysis.

76. A method according to claim 75, wherein said displaying emulates a VAS (Visual Analog Scale) display.

77. A method according to claim 75, wherein said entered value indicates a pain level.

78. A method according to any of claims 75-77, comprising repeating said displaying and said entering a plurality of times for a same type displayed scale.

79. A method according to any of claims 75-77, comprising repeating said displaying and said entering a plurality of times for a different type displayed scale.

80. A monitor network comprising:

a first monitor, worn by a first person, which first monitor generates an alert to said first person; and

a second monitor, worn by a second person, synchronized with said first monitor, which generates an alert to said second person responsive to said first monitor.

81. A network according to claim 80, wherein said first and second monitors are synchronized using a common clock.

82. A network according to claim 80 or claim 81, wherein said first and said second monitors are synchronized using at least one wireless transmission between them.

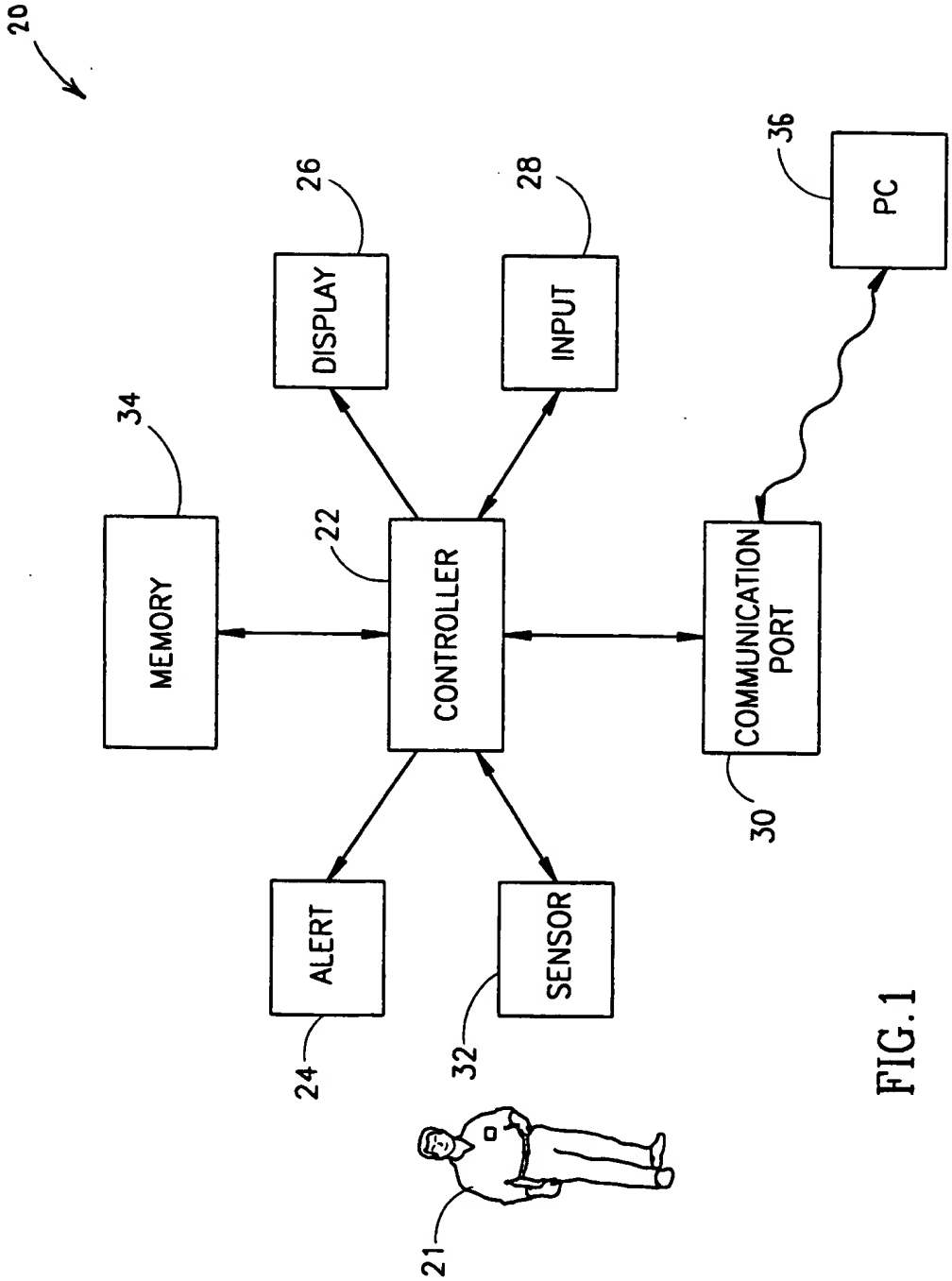
20
DISPLAY
26
INPUT
28
PC
36
MEMORY
34
22
CONTROLLER
COMMUNICATION PORT
30
ALERT
24
SENSOR
32
21

FIG. 1

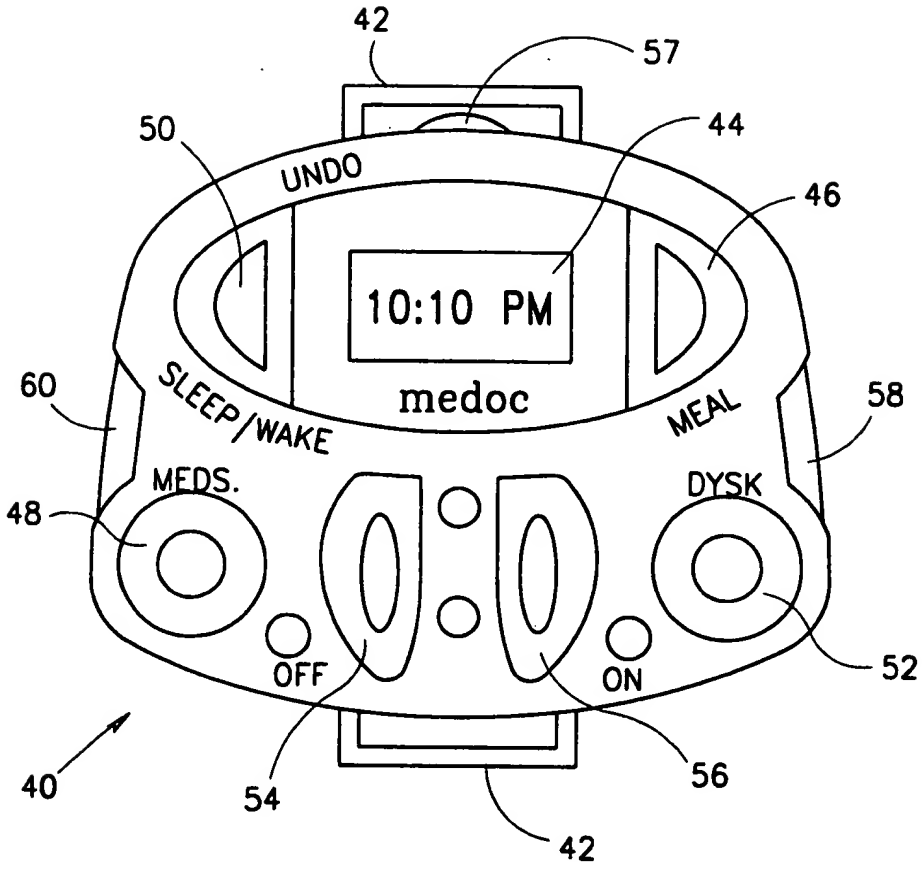

FIG.2A

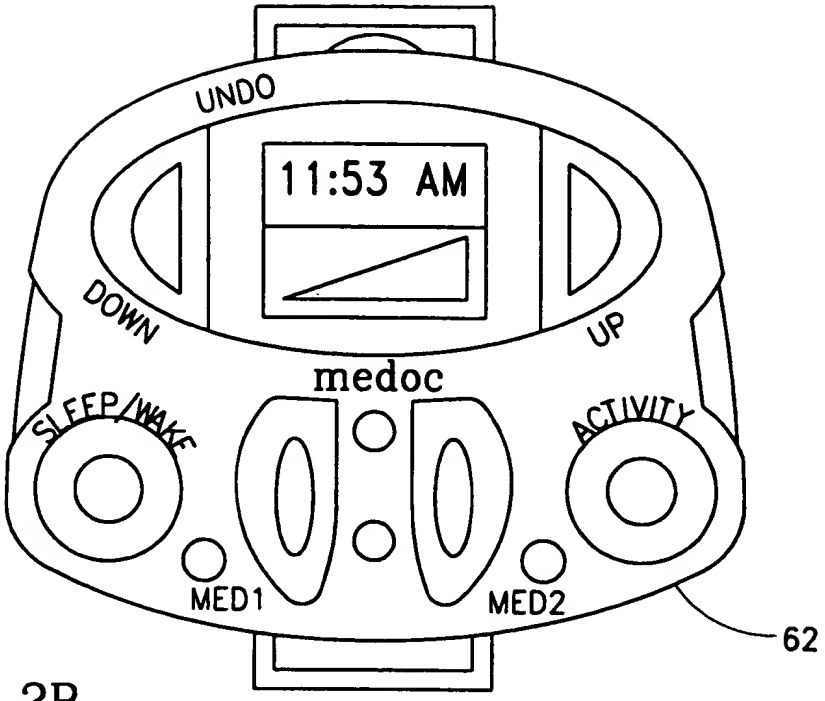

FIG.2B

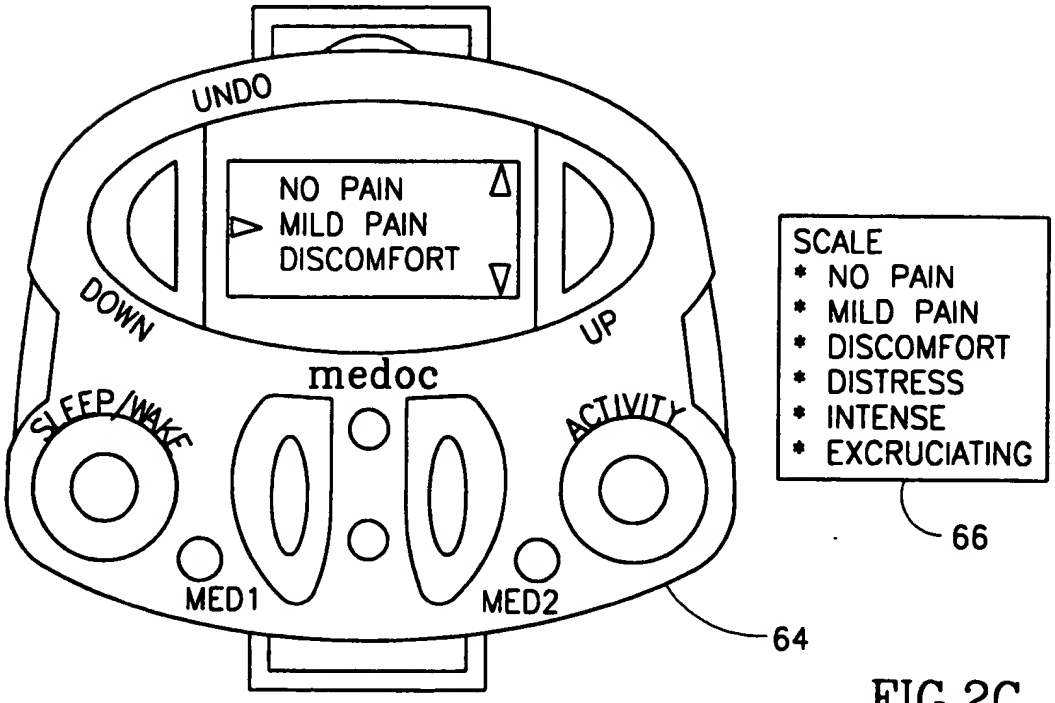

FIG.2C

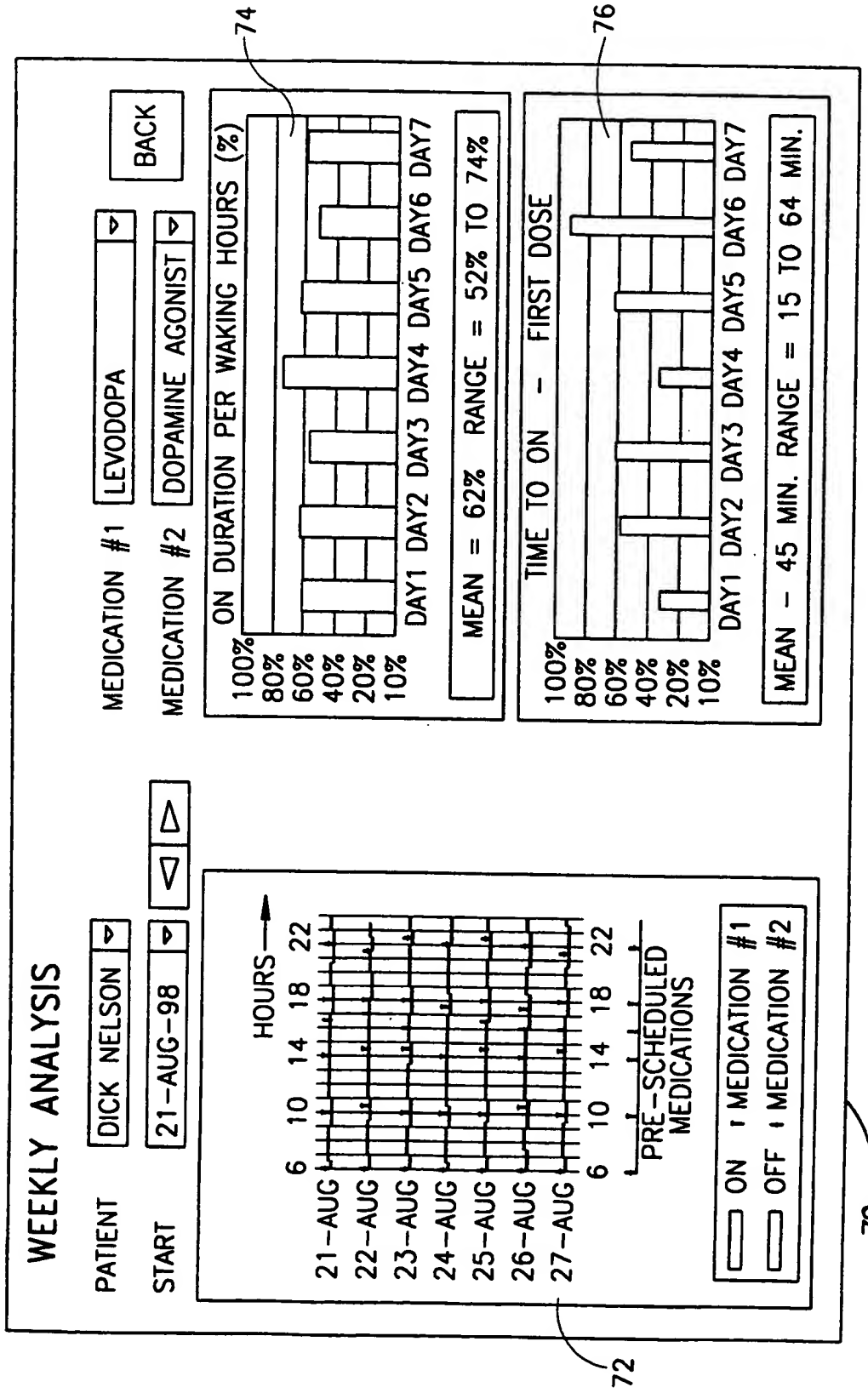

FIG.3A

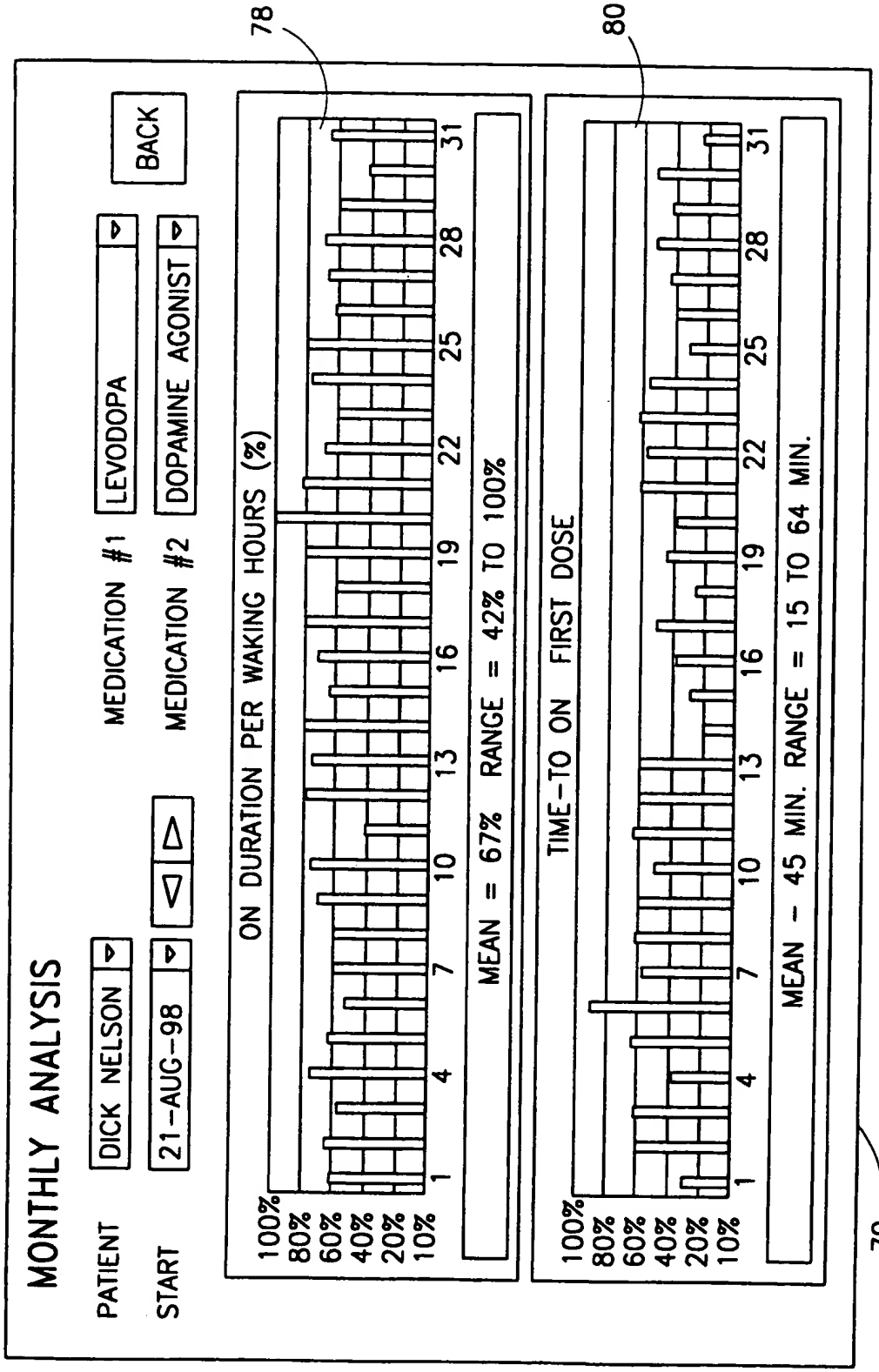

FIG.3B

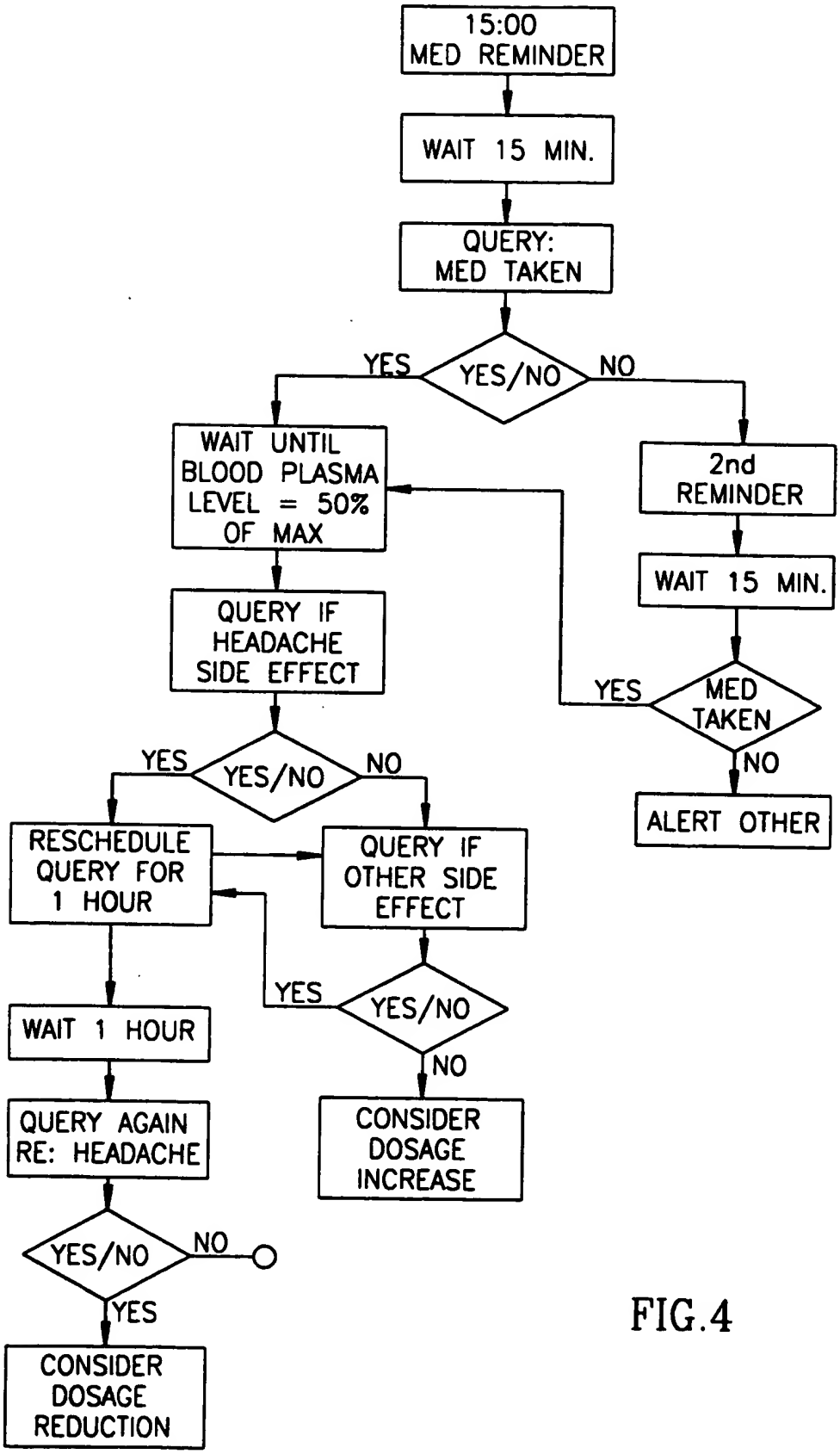

FIG.4

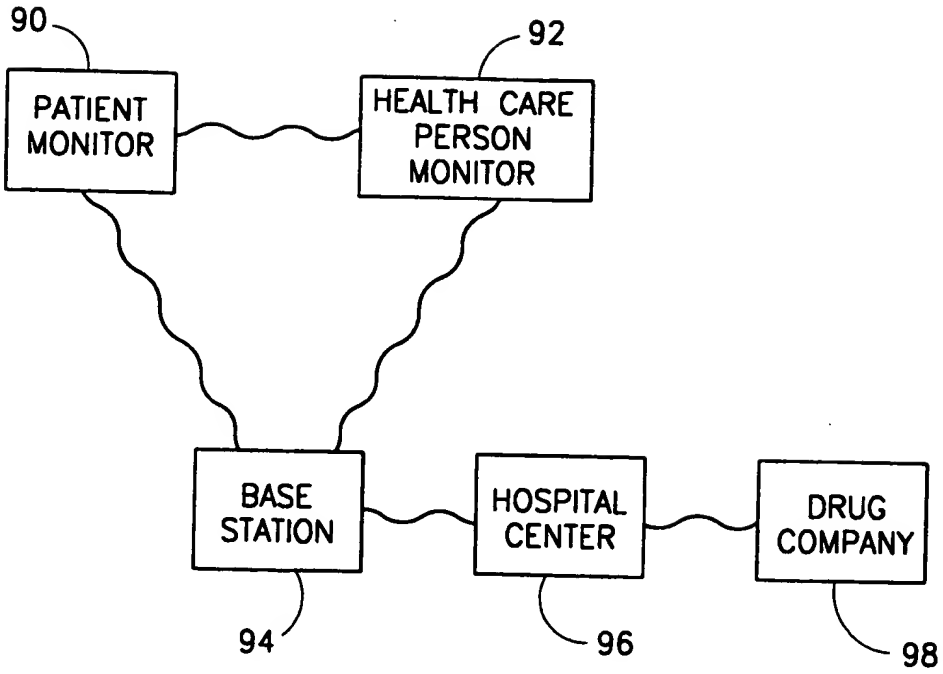

FIG.5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL00/00074

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/00
US CL :600/300

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/900, 903, 904; 600/300, 301, 500-504, 519, 522

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST 1.2

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,596,994 A (BRO) 28 January 1997, entire document.	1-5, 7, 11-60, 62-70, 73-79 --- 61, 80-82
Y	US 5,722,420 A (LEE) 03 March 1998, entire document.	1-5, 8-10, 71, 72
Y,E	US 6,030,342 A (AMANO et al.) 29 February 2000, entire document.	1-6, 10, 21, 23, 34, 38, 71, 72
Y	US 5,544,649 A (DAVID et al.) 13 August 1996, entire document.	1-5, 8-10, 71, 72

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 MAY 2000	26 JUL 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL ASTORINO Telephone No. (703) 306-9067

Form PCT/ISA/210 (second sheet) (July 1998)★